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23117 7590 09/16/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/16/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,397

03/25/2004

Howard R. Levin

JHN-4343-3

5537

TITLE OF INVENTION: METHOD AND SYSTEM TO TREAT AND PREVENT MYOCARDIAL INFARCT EXPANSION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/16/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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P.O. Box 1450
Alexandria, Virginia 22313-1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

23117 7590 09/16/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,397 03/25/2004 Howard R. Levin JHN-4343-3 5537

TITLE OF INVENTION: METHOD AND SYSTEM TO TREAT AND PREVENT MYOCARDIAL INFARCT EXPANSION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$755 \$300 \$0 \$1055 12/16/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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DESANTO, MATTHEW F 3763 604-118000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/808,397	03/25/2004	Howard R. Levin	JHN-4343-3	5537
23117	7590	09/16/2010	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 09/16/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 722 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 722 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/808,397	LEVIN ET AL.	
	Examiner	Art Unit	
	MATTHEW F. DESANTO	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/10/2010 & 09/10/2010.
2. ☒ The allowed claim(s) is/are 1-14 and 20-47.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>09/10/2010</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763

Allowance

The examiner has copied the office action dated 06/10/2010 below, since a new copy of the claims weren't submitted with the IDS dated 09/10/2010. Therefore the claims being allowed are the ones below.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeffry Nelson on June 7, 2010.

The application has been amended as follows:

AMENDMENTS TO THE SPECIFICATION:

Please substitute the following amendment paragraph for paragraph 0040 of the original specification:

[0040] In one embodiment, ~~An object of the invention is to reduce~~ reduces the severity and complications of MI by reducing the infarct expansion. ~~It is the objective of this invention to achieve this goal by~~ which may be achieved by reducing stress in the infarcted ventricle by constraining the heart and reducing the diastolic dilation of the heart. ~~It is the objective of this invention to reduce the~~ The infarct expansion may be

Art Unit: 3763

reduced with a procedure that is practical, simple, easily reversible, and minimally invasive (does not require general anesthesia and surgery).

Art Unit: 3763

AMENDMENTS TO THE Claims:

Claim 1:

A method for treating a heart in a human patient having a pericardial sac comprising:

- a. inserting only a distal tip of a catheter into the pericardial sac of the patient;
- b. infusing fluid through the catheter into the pericardial sac and increasing a fluid pressure in the pericardial sac;
- c. constraining the heart with the infused fluid and the resulting increased fluid pressure to form at least a partial cardiac tamponade, and
- d. reducing dilation of the heart by the constraint on the heart.

Claim 11:

A method to constrain a heart of a mammalian patient, wherein the heart is in a pericardial sac, said method comprising:

- a. inserting only a distal section of a catheter into the pericardial sac, wherein the distal section does not surround the heart;
- b. infusing a fluid from the distal section and into the pericardial sac to form at least a partial cardiac tamponade;

Art Unit: 3763

c. increasing a fluid pressure in the pericardial sac by the infusion of the fluid, and

d. reducing a dilation of the heart by the cardiac tamponade ~~fluid-pressure increase~~ in the pericardial sac.

Cancel claims 15-19

Art Unit: 3763

Claim 20:

A method for treating the heart comprising:

infusing a flowable material into the pericardial sac of the heart, wherein the flowable material flows through a distal tip of a catheter inserted into the pericardial sac and the flowable material contacts tile pericardial sac, wherein only the distal tip of the catheter extends into the pericardial sac,

continuing the infusing at least until the flowable material in the pericardial sac is a sufficient volume to increase a pressure in the sac to form at least a partial cardiac tamponade, and thereby constrain the heart and reduce diastolic dilation of the heart, and

reduce dilation of the heart by the constraint on tile heart resulting from the cardiac tamponade ~~infused flowable material.~~

Claim 27:

A method for treating a heart of a mammalian patient, the method comprising:

infusing a flowable material into a pericardial sac of the heart, wherein the flowable material is inside and in contact with tile pericardial sac, wherein the flowable material is infused from a distal section of a catheter, only the distal section of the catheter extends into the pericardial sac, and the distal section does not surround the heart;

Art Unit: 3763

forming a hydraulic shell around at least a portion of the heart by the infusion of the flowable material into the pericardial sac, wherein the hydraulic shell increases a pressure in the pericardial sac due to the infusion of the flowable material and forms at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade ~~hydraulic shell~~ and thereby reducing dilation of the heart.

Claim 36:

A method for treating a mammalian patient having a dilated heart enclosed inside a pericardial sac comprising:

- a. inserting a distal tip of a catheter into the pericardial sac of the patient, wherein only the distal tip of the catheter enters the pericardial sac;
- b. infusing fluid through the catheter into the pericardial sac, wherein an amount of fluid is infused to substantially increase a fluid pressure in the sac and forms at least a partial cardiac tamponade;
- c. constraining the heart with the cardiac tamponade ~~infusion in the pericardial sac~~ to substantially reduce the dilation of the heart, and
- d. sealing a puncture in the pericardial sac formed to infuse the fluid.

Claim 37:

A method for treating a dilated heart in a pericardial sac of a mammalian patient, the method comprising:

Art Unit: 3763

- a. inserting only a distal section of a catheter in the pericardial sac, wherein the distal section does not surround the heart;
- b. infusing fluid through the catheter into the pericardial sac, wherein an amount of fluid is infused to substantially increase a fluid pressure in the sac and form at least a partial cardiac tamponade;
- c. constraining the heart with the cardiac tamponade infusion in the pericardial sac to substantially reduce the dilation of the heart, and
- d. sealing the pericardial sac.

Claim 38:

A method for reducing expansion of an infarct of a heart in a human patient having a dilated heart enclosed inside a pericardial sac comprising:

- a. inserting only a distal section of a catheter in the pericardial sac of a patient, wherein the distal section does not surround the heart;
- b. infusing the fluid through the catheter into the pericardial sac;
- c. infusing sufficient fluid to cover substantially the entire surface of the heart with the fluid and to substantially increase a pressure in the pericardial sac, and
- d. constraining the heart with the fluid substantially covering the heart to substantially reduce the dilation of the heart, wherein the fluid forms at least a partial cardiac tamponade.

Claim 40:

A method for treating a patient with dilated heart comprising:

Art Unit: 3763

inserting into a pericardial sac surrounding the heart only a distal section of a catheter, wherein the distal section does not surround the heart;

creating a cardiac tamponade of the heart by controlled infusion of a fluid from the distal section of the catheter into the pericardial sac to increase a fluid pressure in the pericardial sac, wherein the fluid is in contact with the pericardial sac;

constricting the heart by the infusion which forms at least a partial cardiac tamponade, and

dilating the heart by the constriction of the heart due to the cardiac tamponade.

Claim 41:

A method for treating a patient with dilated heart comprising:

inserting into a pericardial sac surrounding the heart only a distal section of a catheter and the distal section does not surround the heart;

creating a hydraulic shell around the heart by controlled infusion of a fluid from the distal section of the catheter into the pericardial sac, wherein the fluid is in contact with the pericardial sac and the hydraulic shell increases a fluid pressure in the pericardial sac;

constricting the heart by the infusion which forms at least a partial cardiac tamponade, and

dilating the heart by the constriction of the heart due to the cardiac tamponade.

Claim 42:

A method for treating a heart in a mammalian patient comprising:

Art Unit: 3763

extending a catheter through a blood vessel adjacent a pericardial sac of the heart;

puncturing a wall of the blood vessel and the pericardial sac with a distal section of the catheter, wherein only the distal section extends into the pericardial sac and the distal section does not surround the heart;

infusing a flowable material from the distal end of the catheter to the pericardial sac of the heart;

forming a hydraulic shell around at least a portion of the heart, by the infusion of the flowable material into the pericardial sac, wherein the hydraulic shell increases a fluid pressure in the pericardial sac and thereby forms at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade formed by the hydraulic shell.

Claim 45:

A method for treating a mammalian patient having a dilated heart enclosed inside a pericardial sac comprising:

inserting only a distal section of a catheter into the pericardial sac of the patient, wherein the distal section does not surround the heart;

infusing fluid through the catheter into the pericardial sac to increase a fluid pressure in the pericardial sac and form at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade ~~increased fluid pressure in the pericardial sac~~ to substantially reduce the dilation of the heart.

Claim 46:

A method for reducing abnormal dilation of a heart to treat at least one of acute myocardial infarction and heart failure conditions, the method comprising:

positioning a fluid infusion device such that at least one opening at a distal section end is inside the pericardial sac and a proximal end of the device is outside of the patient, wherein only the distal section extends into the sac and the distal section does not surround the heart,

pumping fluid through the device to infuse the fluid into the pericardial sac to increase a pressure in the pericardial sac and form at least a partial cardiac tamponade,
constraining the heart with the cardiac tamponade infusion and,
sealing the pressurized fluid within the pericardial sac;

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, 20-47 are drawn to a method of infusing a fluid into the pericardial sac, classified in class 604, subclass 500.
 - II. Claims 15-19 are drawn to a infusion system, classified in class 604, subclass 131.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 3763

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a totally different process such as a teaching model.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Jeffry Nelson on June 7, 2010 a provisional election was made without traverse to prosecute the invention of Group I. Affirmation of

Art Unit: 3763

this election must be made by applicant in replying to this Office action. Claims 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found were method claims that dealt with inserting a short portion of a catheter into pericardial sac and infusing fluid into the pericardial space through the catheter so that pressure would increase and constrain the heart (cardiac tamponade).

The independent claims also include other patentable subject matter in combination with the other elements or steps of the claim not mention in the above paragraph.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto

/Matthew F DeSanto/

Primary Examiner, Art Unit 3763